

# PERIO-FLUSH Solution for Periodontal Pocket Irrigation

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# For everyday battles against periodontal disease



Rinses, cleanses, and purifies periodontal pockets

Inhibits colonization by pathogenic microorganisms

Reduces the concentration of anaerobic bacteria

> Diminishes bleeding from pathological pockets

Decreases the depth of pathological pockets



Comparison of the prevalence of selected chronic diseases according to a WHO report

Periodontal pocket irrigation takes 2–3 minutes and can accompany many daily in-office procedures.

More than 2/3 of Poles over the age of 35 suffer from periodontal disease meaning they are in your clinic every day.

Only regular irrigation of periodontal pockets allows for full elimination of disease symptoms. This procedure should be performed every 1-3 months until the pocket depth is reduced to less than 5 mm.



Source: "Choroba próchnicowa i stan tkanek przyzębia populacji polskiej. Podsumowanie wyników badań z lat 2016-2019" (Carious disease and the condition of periodontal tissues in the Polish population. Summary of research results from 2016–2019). Scientific editor: Dorota Olczack-Kowalczyk

Source: "Now is the time to take gum disease seriously: A roadmap for improving oral health in the United States", Economist Impact, 2023

## POCKET IRRIGATION AFTER TARTAR REMOVAL



Evaluate the status and depth of periodontal pockets. Overlooking chronic inflammation can result in missed treatment opportunities.

It is easy to overlook chronic inflammation when the gingiva lacks swelling and redness is slight.





Periodontal pocket irrigation effectively cleaned pockets, enabling gingival reattachment to roots, epithelial attachment regeneration, and a reduction in pocket depth.

Repeat irrigation of pockets every 1–3 months, aiming for a pocket depth of approximately 4-5 mm.

## AROUND TEETH WITH CHALLENGING ERUPTION



Across-section of a periodontal pocket with inflammation caused by the obstructed eruption of a third molar (lower eighth).





The periodontal pocket is cleaned, inflammatory debris completely removed with no visible swelling. Proper rinsing of the pocket can save the patient from surgical removal of overgrown gingiva.

## NEAR CLASS II RESTORATIONS WITHOUT ADEQUATE CONTACT POINTS



A cross-section of a periodontal pocket with inflammation caused by food debris in the interdental space between the lower molars.





Periodontal pocket irrigation effectively cleaned pockets, enabling gingival reattachment to roots, epithelial attachment regeneration, and a reduction in pocket depth. Consider replacing a filling to restore the contact point.

## **AROUND FIXED ORTHODONTIC APPLIANCES**



A cross-section of an inflamed periodontal pocket near fixed orthodontic appliances, caused by food debris accumulation. Difficult or even impossible cleaning of this area always leads to gingivitis and periodontitis.



The PERIO-FLUSH applicator is inserted deeply into the base of the periodontal pocket during irrigation.

For the irrigation of periodontal pockets



The periodontal pocket is cleaned, inflammatory debris completely removed with no swelling.

## INFLAMED AREAS WHERE TEETH ARE TO BE EXTRACTED



Inflammation of periodontal pockets, caused by carious destruction of the hard tissues of the tooth and abundant dental deposits.

Before tooth extraction, irrigate inflamed pockets to ensure a clean entry for sterile extraction tools, reducing the risk of post-extraction complications, includingdry socket.

The PERIO-FLUSH applicator is inserted deeply into the base of the periodontal pocket during irrigation.



Inflammatory debris from periodontal pockets is removed. Clean entry of sterile extraction instruments, e.g. the lateral lever, is ensured.

## UNDER FIXED PROSTHETIC RESTORATIONS (BRIDGES)



A cross-section showing inflammation caused by food debris accumulation under the bridge span of the fixed prosthetic restoration and the gingiva. Difficult or even impossible cleaning of this area always leads to gingivitis.



The PERIO-FLUSH applicator is used for irrigation from the vestibular, palatal, and interdental sides.

For the irrigation of periodontal pockets



Irrigation clears the space under the bridge span, alleviating inflammation, swelling, and discomfort.

#### **PERIO-FLUSH**

## Solution for periodontal pocket irrigation in a syringe dispenser MD Medical device

PERIO-FLUSH is a ready-to-use liquid solution designed for cleaning and irrigating periodontal pockets. It serves as an adjunct in the non-surgical management of periodontal disease. It effectively eliminates solid debris from the pocket, and does not hinder the reformation of connective tissue attachment.

#### **MECHANISM OF ACTION**

PERIO-FLUSH is an isotonic solution of mineral salts with the addition of a quaternary ammonium compound (domiphen bromide). Its mechanism of action is primarily a mechanical removal of inflammatory debris from the periodontal pocket.

#### **INDICATIONS FOR USE**

- Inflammation in periodontal pockets, especially:
- near class II restorations or areas with missing contact points.
- around teeth with challenging eruption, particularly third molars ("eights").
  prior to extraction procedures, specifically in pockets adjacent to the tooth set for removal.
- in areas around crowns.
- in areas around teeth supporting denture clasps, brackets, or arches of removable orthodontic appliances.
- around fixed orthodontic appliances.
- in cases of soft tissue inflammation under prosthetic works such as bridges, under dentures, and removable orthodontic appliances.
- for irrigation of periodontal pockets following tartar removal.

#### **GENERAL DEVICE HANDLING INSTRUCTION**

If possible, bring the PERIO-FLUSH solution to body temperature to minimise patient discom fort during application. Unscrew the cap and attach the disposable applicator by screwing it tight on the luer-lock of the syringe. Make sure the dispensing system is working correctly by gently pressing on the syringe plunger away from the patient's mouth until a drop of the product appears. If the solution does not flow, replace the applicator with a new one.

If the process is successfully completed, you can start working with the patient. To apply the product, gently insert the applicator down to the base of the periodontal pocket. After positioning the applicator at the bottom of the periodontal pocket, withdraw the tip approximately 1–2 mm away from the pocket's base. Then, start the rinsing process by gradually pressing the syringe's plunger. Below you will find detailed instructions on how to proceed in different clinical cases. Continue until the liquid flowing out of the pocket is clear.

After the procedure is finished, instruct the patient to spit out any remaining product and rinse their mouth with mouthwash, preferably MUSON solution. Detach and dispose of the applicator after use and the empty syringe according to the instructions.

#### **INSTRUCTIONS FOR USE**

#### **INFLAMMATION OF PERIODONTAL POCKETS:**

#### Near class II restorations or areas with missing contact points

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Remove solid dental deposits, taking care not to damage the root cementum layer. While irrigating, move the applicator around all the tooth roots, keeping the tip close to the bottom of the pocket. Encircle each tooth and its individual roots, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue irrigating as long as there is no inflammatory content or tartar remains flowing out of the pocket.

Around teeth with challenging eruption, particularly third molars ("eights")
 Ask the patient to rinse their mouth with mouthwash, preferably MUSON

solution. Remove food debris with a probe or another instrument. While irrigating, move the applicator around the tooth, keeping the tip as deep as possible. Encircle each tooth, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue irrigating as long as there is no inflammatory content or solid debris flowing out of the pocket.

#### Prior to extraction procedures, specifically in pockets adjacent to the tooth set for removal

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. While irrigating, move the applicator around the tooth, keeping the tip close to the bottom of the pocket. Encircle each tooth, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue irrigating as long as there is no inflammatory content or tartar remains flowing out of the pocket. Ensure that the area, especially where extraction instruments will be used, is thoroughly cleaned.

#### • In areas around crowns

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Remove food debris with a probe or another instrument, also from the space under the crown. While irrigating, move the applicator around the tooth and to the space under the crown, keeping the tip as deep as possible. Encircle each tooth, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue rinsing as long as there is no inflammatory content or solid debris flowing out of the pocket or from under the crown. When awaiting a new dental restoration, it is advisable to fill the retention areas beneath the crown. This step helps to limit the accumulation of food residues in these spaces.

#### In areas around teeth supporting denture clasps, brackets, or arches of removable orthodontic appliances

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Remove solid dental deposits, taking care not to damage the root cementum layer. Temporarily adjust the denture base or clasp to eliminate pressure points on the mucosa. Plan for a new prosthetic restoration. Rinse the swollen surface of the gingiva and then the pocket by moving the applicator around the tooth,

keeping the tip close to the bottom of the pocket. Encircle each tooth, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue irrigating as long as there is no inflammatory content or tartar remains flowing out of the pocket.

#### Around fixed orthodontic appliances

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Remove solid dental deposits, taking care not to damage the root cementum layer. Adjust the bracket to create a clearance (an additional 2 mm is usually enough). While irrigating, move the applicator around the tooth, keeping the tip close to the bottom of the pocket. Encircle each tooth, ensuring that all inflammatory content is thoroughly flushed out from the periodontal pockets. Continue irrigating as long as there is no inflammatory content or tartar remains flowing out of the pocket.

## IN CASES OF SOFT TISSUE INFLAMMATION UNDER PROSTHETIC WORKS SUCH AS BRIDGES

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solu tion. Use a probe or another instrument to remove food debris from the spaces between the bridge span and the gingiva, avoiding excessive pressure on the gingiva. Insert the applicator from the right side of the mouth under the bridge span. Begin irrigating, moving the applicator along the span from one pillar tooth to the other. Aim to keep the applicator tip as deep as possible under the bridge to ensure thorough cleaning. If necessary, insert the applicator from the vestib ular side and continue irrigating until all the inflammatory debris is washed away. Continue irrigating as long as there is no inflammatory content or solid debris flowing from under the bridge span.

#### IN CASES OF SOFT TISSUE INFLAMMATION UNDER DENTURES, AND REMOVABLE ORTHODONTIC APPLIANCES

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Temporarily adjust the denture or appliance base to eliminate pressure points on the mucosa. Make sure the surface of the base of the denture or appliance is smooth. If the fit of a prosthetic restoration proves unsuccessful, it is advisable to schedule a new prosthetic restoration. Rinse the swollen gingival surface.

#### IRRIGATING PERIODONTAL POCKETS FOLLOWING TARTAR REMOVAL

Ask the patient to rinse their mouth with mouthwash, preferably MUSON solution. Remove solid dental deposits, taking care not to damage the root cementum layer. While irrigating, move the applicator around the tooth, keeping the tip as deep as possible. After tartar removal, encircle each treated tooth, ensuring that all inflammatory content and debris have been effectively rinsed away. Continue irrigating as long as there is no inflammatory content or tartar remains flowing out of the pocket.

#### COMPOSITION

Purified water, domiphen bromide, sodium chloride, potassium chloride, calcium chloride, apple flavouring, mint flavouring.

#### CONTRAINDICATIONS

Do not use in patients with a known hypersensitivity to any of the ingredients.

#### UNDESIRABLE SIDE EFFECTS

None known. However, an allergic reaction cannot be excluded in particularly sensitive individuals. In case of an allergic reaction, stop using the device.

#### **RESTRICTIONS ON USE, INTERACTIONS**

Do not use for rinsing root canals. Do not use if the syringe or applicator is suspected to be defective or damaged. Do not use if any change is observed in the product's properties.

#### **PRECAUTIONS FOR PATIENTS**

Avoid contact with eyes. In case of contact, rinse with plenty of water. If an aller- gic reaction occurs, cease using the product. Consult a professional for advice if necessary.

#### **PRECAUTIONS FOR DENTAL PERSONNEL**

Always wear personal protective equipment (PPE) such as gloves, a face maskand goggles. Avoid contact with eyes. In case of contact, rinse with plenty of water. If an allergic reaction occurs, cease using the product. Consult a professional for advice if necessary. The applicators supplied with the product are designed with blunt tips to minimize the risk of injury. However, they should still be handled with caution to ensure safe usage.

#### **ADVICE FOR DENTAL PERSONNEL**

The product is intended for use by qualified dental personnel in the general patient population. To minimise patient discomfort, it is recommended to warm the product to body temperature before applying it to the periodontal pocket. Always advise the patient of the need to maintain proper oral hygiene.

#### WARNINGS

Protect the syringe surface from contamination. Avoid heat sterilising or immersing the syringe in disinfectants. Do not use the syringe if it becomes contaminated. The applicator and syringe dispenser are disposable and intended for singlepatient use only. Keep out of the reach of children and unauthorised individuals. Use as directed by the manufacturer. Do not use beyond the expiration date.

#### STORAGE

Protect the syringe against mechanical damage. Store at a temperature below 25°C. Do not overheat. Do not freeze.

For use by dentists and qualified dental personnel only.

## EFFICACY AND SAFETY OF THE PERIO-FLUSH MEDICAL DEVICE PROVEN IN A CLINICAL STUDY

Clinical study identifier	UR.DNB.4501.0001.2018 clinical study
Clinical study title	"Określenie skuteczności preparatu do płukania kieszonek przyzębnych PERIO-FLUSH" (Efficacy of PERIO-FLUSH periodontal pocket irrigation solution).
Clinical study type	Single-centre, with a control group, non-randomised
Clinical study start date	9 April 2018
Clinical study end date	7 January 2019

#### **INVESTIGATION SUBJECT AND OBJECTIVES**

The clinical study was designed to assess the effectiveness of PERIO-FLUSH as an adjunct in the treatment of periodontitis, analysing:

- 1. A reduction of bacterial flora in periodontal pockets post-scaling and irrigating with PERIO-FLUSH.
- 2. PERIO-FLUSH's impact on periodontal indices and parameters: API, mSBI, PD, and CAL.

#### PARTICIPANT CHARACTERISTICS

Table 1: Number of participants and participant demographics

	51					
Sov			Female	34		
Sex			Male	17		
			1	1		
		30-39 years old	40-50 years old	51-65 years old		
Age, females		9	5	20		
Age, males		5	3	9		
BMI	-10 5	10 5 24 0	25 0 20 0	220.0		
	< 18,5	18,5-24,9	25,0-30,0	>30,0		
	0	12	22	17		
			VEC	22		
Genetic burden		YES		22		
			29			
Smoking		YES		31		
			20			
Chucuic chucco		YES		16		
Chronic stress			35			
		YES		11		
Concurrent cardiovascular diseases		NO		40		
Periodontal diagnosis		Aggressive periodontitis		15		
		Chronic periodontitis		36		
Average number of	20,4					
Average number of	3,5					
Average number of teeth lost due to periodontal disease				4,2		

#### **INVESTIGATION DESIGN**

The clinical study included the following steps:

- 1. Patient examination; Patient qualification.
- 2. Periodontal examination: assessing oral hygiene (API), inflammation intensity (mSBI), pocket depth (PD), and connective tissue attachment level (CAL).
- 3. Random selection of investigated and control pockets;  $\text{PD} \geq 5 \text{ mm}.$
- 4. Microbiological swab collection from both pockets using paper points.
- 5. Scaling.
- 6. Irrigating investigated/control pockets with PERIO-FLUSH.
- 7. Swab re-collection.
- 8. Follow-up after 7–14 days. Re-evaluation of periodontal parameters (API, mSBI, PD, CAL), swab re-collection for microbiological examination.

PERIO-FLUSH effectively removed deposits from 98% of treated pockets.

It reduced the concentration of anaerobic bacteria in 80.4% of the pockets, averaging a 79% decrease.

Regarding periodontal pocket depth, there was a reduction in 60.8% of patients at the follow-up, with no change in 31.3%. The average decrease in pocket depth across the investigated group was 1.3 mm post-treatment.

PERIO-FLUSH did not interfere with connective tissue attachment restoration.

Irrigation with PERIO-FLUSH showed a significant reduction in bleeding at the follow-up visit.

The clinical study confirmed that PERIO-FLUSH is a safe and effective adjunct to the standard scaling process for treating periodontal disease. No adverse reactions or need for additional medical procedures beyond the prescribed plan were reported during the clinical study.



ARKONA Laboratorium Farmakologii Stomatologicznej Nasutów 99C, 21-025 Niemce, Poland, EU +48 887 883 005, +48 664 407 296

Export department: export@arkonadent.com



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